SYNTHES®

FEB - 8 2012

K120083

3.0 510(k) Summary

Sponsor:

Synthes
Thomas N. Shea
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6809

Device Name: Set Screw for Ti Trochanteric Fixation Nail (TFN)

Classification: Product Code – HSB/HWC, Rod, Fixation, Intramedullary and Accessories, Class II, §888.3020 – (Intramedullary fixation rod.)

Predicate Devices: Synthes Trochanteric Fixation Nail (TFN) Screw **K092646**

Synthes Trochanteric Fixation Nail (TFN) **K011857**

Smith & Nephew, Inc. TriGen InterTAN° **K040212**

Device Description: The Set Screw for Ti Trochanteric Fixation Nail (TFN) is an additional offering for use with the existing TFN System. The Set Screw prevents sliding and rotation of the head element (TFN Screw or helical blade) within the nail for fixation of proximal femur fractures.

Intended Use: The Set Screw for Ti Trochanteric Fixation Nail (TFN) is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures and combinations thereof. The long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.

Substantial Equivalence: Information presented supports substantial equivalence of the Set Screw for Ti Trochanteric Fixation Nail (TFN) to the predicate devices, Synthes Trochanteric Fixation Nail, Synthes Trochanteric Fixation Nail Screw, and the Smith & Nephew, Inc. TriGen InterTAN°. The proposed set screw has the same indications for use, is similar in shape/design and incorporates the same fundamental technology.

Axial static testing was conducted to demonstrate the comparable mechanical performance of the subject device, Set Screw for Ti TFN compared to the predicate. The mechanical testing was designed to assess the peak slip load of the proposed device.

The results of the mechanical evaluation confirm that the subject device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes
% Mr. Thomas Shea
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

FEB - 8 2012

Re: K120083
Trade/Device Name: Set Screw for Ti Trochanteric Fixation Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod.
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: January 10, 2012
Received: January 12, 2012

Dear Mr. Shea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use

510(k) Number (if known): K120083

Device Name: Set Screw for Ti Trochanteric Fixation Nail (TFN)

Indications for Use:

The Set Screw for Ti Trochanteric Fixation Nail (TFN) is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures and combinations thereof. The long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120083